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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,710	02/09/2009	Louise D. McCullough	P71492US0	3109

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Fox Rothschild LLP
Phlla, Biotech Group
2000 Market Street
Philadelphia, PA 19103

EXAMINER	
HAYES, ROBERT CLINTON	
ART UNIT	PAPER NUMBER
1649	
MAIL DATE	DELIVERY MODE
12/29/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/593,710	MCCULLOUGH ET AL.	
	Examiner	Art Unit	
	ROBERT C. HAYES	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-6 and 10-23* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-6 and 10-23* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/16/11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed 11/16/11 has been entered.

2. Applicant's arguments filed 11/16/11 have been fully considered but they are not deemed to be persuasive.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1, 2, 5, 6 and new claims 10-15 & 18-23 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record in Paper No: 20110610, and as follows. **This is a written description rejection**.

Applicants argue on pages 4-6 of the response that "Applicants need not 'describe', in the sense of 35 U.S.C. 112, all things that are encompassed by the claims", cites *Gentry Gallery Inc v. Berkline Corp, Lockwood v. American Airlines, In re Alton, Ralston-Purina Co. v. Far-Mar Co*, and Witters et al. In contrast to Applicants' assertions, the pending rejection is analogous with that held by the court in *University of Rochester v. G.D. Searle & Co., Inc.* (69 USPQ2d, 1886 (CAFC 2004)), in which it was upheld that use of "unspecified compounds" in a method of

treatment [i.e., an undefined formulation for treating] does not meet the written description requirements under 35 U.S.C. 112, first paragraph, because no known or disclosed correlation between function and structure, or some combination of such characteristics of the compounds required for use in the claimed method were described in the specification, which the current claims also fail to define.

MPEP 2111.01(II) makes clear that:

"Though understanding the claim language may be aided by explanations contained in the written description, it is important not to import into a claim limitations that are not part of the claim. For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment." Superguide Corp. v. DirecTV Enterprises, Inc., 358 F.3d 870, 875, 69 USPQ2d 1865, 1868 (Fed. Cir. 2004).

Additionally, the courts have held that *negative limitations* that exclude compounds do not meet the requirements of 35 U.S.C. 112 because it attempts to claim the invention by excluding what was not invented rather than what was invented. In re Schechter, 205 F2d 185, 98 USPQ 144 (CCPA 1953) (i.e., as it especially relates to claims 2, 5, 15 & 18).

As previously made of record, the issue remains that without ***structurally defining*** what constitutes the *claimed genus* of "compounds" that are putative "AMPK inhibitors" that reasonably are *involved in "neuroprotection"* of neurons containing glutamate receptors, one of ordinary skill in the art would not know when they are in possession of the "compounds" required to practice the currently claimed method. For example, again one skilled in the art cannot even reasonably visualize or predict what critical amino acid residues would structurally characterize the genus of "compounds" that would be peptides, let alone what critical residues would constitute "non-peptides, other biologically-derived material or small molecules, required to practice the claimed invention.

In summary, because the specification fails to provide a *representative number of species* to show applicant is in possession of using the *currently undefined genus of compounds* required to practice the currently generic method, the written description requirements under 35 U.S.C. 112, first paragraph are not met. See MPEP 2163.

Accordingly, *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, 1117, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, *as of the filing date sought*, he or she was in possession *of the claimed invention*". "The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed* [emphasis added]".

5. Claims 1-2, 5-6 and new claims 10-15 & 18-23 stand rejected under 35 U.S.C. 102(b) as being anticipated by Tracey et al (U.S. Patent (IDS Ref # 3), for the reasons made of record in Paper No: 20110610, and as follows

Applicants argue on pages 6-7 of the response that "Tracey, unlike Applicants' specification, provides no data or support whatsoever for any possible neuroprotective activity of AMPK inhibitors". In response to applicant's argument that the reference fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., assays for determining neuroprotective activity of AMPK inhibitors) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Nevertheless, the same population of patients experiencing stoke/ischemia are administered a compound that is generically encompassed by the broad scope of compounds to

be administered (i.e., broader than even an alleged laundry list of compounds), which is why a *prima facie* case for lack of novelty is clearly established by the Examiner.

In summary, Tracey et al. teach treatment of ischemic tissue damage with non-peptide metabolic modulators, such as AMPK inhibitors (i.e., column 3 (lines 14-20) & column 8 (lines 15-19, 29-30 & 62-65)).

6. Claims 1-3, 5-6 and new claims 10-16 & 18-23 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Tracey et al (U.S. Patent 6,423,705), in view of Kim et al. (2002; IDS Ref #6), for the reasons made of record in Paper No: 20110610, and as follows.

Applicants argue on pages 7-9 of the response that "impermissible hindsight in light of Applicants' specification" is used. In contrast to Applicants' assertions, obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and KSR International Co. v. Teleflex, Inc., 550 U.S. 398, 82 USPQ2d 1385 (2007).

In response to Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Moreover, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of

the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See Ex parte Obiaya, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Thus, Applicants' arguments are not persuasive

In summary, Tracey is as described above. However, Tracey et al do not mention use of the AMPK inhibitors, compound C or C75.

Kim et al teach administration of the AMPK inhibitor C75 (i.e., a FAS inhibitor and CPT-1 stimulator; see pg. 6 of the specification) to mouse subjects (e.g., pgs. E867, E868, E870 & E872) which effects FAS expression in neurons (i.e., as it relates to claim 3). However, Kin et al do not teach administration of C75 to subjects experiencing stroke/ischemia.

It would have been obvious to one of ordinary skill in the art at the time of filing Applicants' invention to use the AMPK inhibitor of Kim in Tracey's method of treating ischemia with AMPK inhibitors with a reasonable expectation of success.

7. Claims 1-2, 4-6 and new claims 10-15 & 17-23 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Tracey et al (U.S. Patent 6,423,705), in view of Leon et al. (2002; IDS Ref #7), for the reasons made of record in Paper No: 20110610, and as discussed above in preceding *pp* # 6.

In summary, Tracey is as described above. However, Tracey et al do not mention use of the AMPK inhibitors, compound C or C75.

Leon et al teach administration of the AMPK inhibitor Compound C to rat subjects (e.g., pgs. 525-526) which effected excitation in glutamatergic neurons administered melatonin (i.e., as

it relates to claim 4). However, Leon et al do not teach administration of Compound C to subjects experiencing stroke/ischemia.

It would have been obvious to one of ordinary skill in the art at the time of filing Applicants' invention to use the AMPK inhibitor of Leon in Tracey's method of treating ischemia with AMPK inhibitors with a reasonable expectation of success, because ischemia is characterized by over-excitation of glutamate receptors.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ali Salimi, can be reached on (571) 272-0909. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-4797 (toll-free).

/ROBERT C. HAYES/
Primary Examiner, Art Unit 1649
December 27, 2011